AD	ı	

Award Number: DAMD17-01-1-0091

TITLE: Bone Mineral Density, Sex Steroid Genes, Race and

Prostate Cancer Risk

PRINCIPAL INVESTIGATOR: Francesmary Modugno, Ph.D., M.P.H.

CONTRACTING ORGANIZATION: University of Pittsburgh

Pittsburgh, Pennsylvania 15262

REPORT DATE: September 2002

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;

Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Magaziners and Rudet Paperwork Reduction Project (0704-0188) Washington DC 20503.

Management and Budget, Paperwork Reduction Proje	ct (0704-0188), Washington, DC 20503			
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AN	D DATES COVERE	:D
	September 2002	Annual (1 Sep	01 - 31 Au	g 02)
4. TITLE AND SUBTITLE			5. FUNDING N	IUMBERS
Bone Mineral Density, Sex St	eroid Genes, Race and Pro	ostate Cancer	DAMD17-01	-1-0091
Risk				
KISK				
6. AUTHOR(S)				
Francesmary Modugno,	Ph.D., M.P.H.			
7. DEDECTION OF CANUTATION MARK	IE(O) AND ADDRESO(EO)		O DEDECORAGE	G ORGANIZATION
7. PERFORMING ORGANIZATION NAM	IE(S) AND ADDRESS(ES)		REPORT NU	
TT-do-college of Direct			1121 0117 110	WIDE
University of Pittsb	_			
Pittsburgh, Pennsylv	ania 152 62			
E-Mail: fm@cs.cmu.edu				
9 SPONSORING / MONITORING AGE	NCV NAME(S) AND ADDRESS(ES	31	10 SPONSORI	NG / MONITORING
9. SPONSORING / MONITORING AGE	NCY NAME(S) AND ADDRESS(ES	6)		NG / MONITORING
				NG / MONITORING EPORT NUMBER
U.S. Army Medical Resear	ch and Materiel Comma			
	ch and Materiel Comma			
U.S. Army Medical Resear	ch and Materiel Comma			
U.S. Army Medical Resear	ch and Materiel Comma			
U.S. Army Medical Resear Fort Detrick, Maryland	ch and Materiel Comma			
U.S. Army Medical Resear	ch and Materiel Comma			
U.S. Army Medical Resear Fort Detrick, Maryland	ch and Materiel Comma			
U.S. Army Medical Resear Fort Detrick, Maryland	ch and Materiel Comma			
U.S. Army Medical Resear Fort Detrick, Maryland	ch and Materiel Comma 21702-5012			
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY S	ch and Materiel Comma 21702-5012	and		REPORT NUMBER
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES	ch and Materiel Comma 21702-5012	and		REPORT NUMBER
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY S	ch and Materiel Comma 21702-5012	and		REPORT NUMBER
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY S	ch and Materiel Comma 21702-5012	and		REPORT NUMBER
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY S	ch and Materiel Comma 21702-5012 TATEMENT ase; Distribution Unl	and		REPORT NUMBER
U.S. Army Medical Resear Fort Detrick, Maryland 11. SUPPLEMENTARY NOTES 12a. DISTRIBUTION / AVAILABILITY S Approved for Public Rele	ch and Materiel Comma 21702-5012 TATEMENT ase; Distribution Unl	limited	AGENCY F	12b. DISTRIBUTION CODE

The goal of this project is to determine whether bone mineral density (assumed to be an integrated marker of sex steroid hormone exposure) is a risk factor for prostate cancer; and (2) to identify prostate cancer susceptibility alleles among genes in the sex steroid pathway. To address these aims, we are undertaking a case-control study of African American and Caucasian men in Pittsburgh, PA and Baltimore, MD. Cases are 100-150 African American and 150 Caucasian men with histologically-confirmed prostate cancer. Controls are age and race frequency-matched men who have a PSA < 3.0 ng/mL. Hip, spine and total body BMD is measured by Dualenergy X-ray Absorptiometry (DXA). Blood is used to obtain DNA. Polymerase Chain Reaction (PCR) techniques will be used to determine allelic distributions of genotypes for sex steroid metabolism, biosynthesis and action genes. Risk factor data are obtained by an in-person interview. Pathology information will be collected using standardized medical abstraction and all pathology will be confirmed by a central pathologist. Upon completion recruitment and data collection, we will evaluate the role of BMD and candidate genotypes in prostate cancer risk by race. We will further examine the interaction between BMD and genotypes to evaluate the hormonal environment – gene interaction and its effect on prostate cancer risk.

14. SUBJECT TERMS			15. NUMBER OF PAGES
prostate cancer, prevent	c epidemiology, etiology,	62	
gene-gene and gene-envir	ic risk, bone mineral	16. PRICE CODE	
density, sex steroid hor	mone		
17. SECURITY CLASSIFICATION	18. SECURITY CLASSIFICATION	19. SECURITY CLASSIFICATION	20. LIMITATION OF ABSTRACT
OF REPORT			
Unclassified Unclassified		Unclassified	Unlimited

Table of Contents

Cover	1
SF 298	2
Table of Contents	3
Introduction	4
Body	4
Key Research Accomplishments	6
Reportable Outcomes	6
Conclusions	6
References	6
Appendices	9

INTRODUCTION:

The goal of this project is to determine whether bone mineral density (assumed to be an integrated marker of sex steroid hormone exposure) is a risk factor for prostate cancer; and (2) to identify prostate cancer susceptibility alleles among genes in the sex steroid pathway. To address these aims, we are undertaking a case-control study of African American and Caucasian men in Pittsburgh, PA and Baltimore, MD. Cases are 100-150 African American and 150 Caucasian men with histologically-confirmed prostate cancer. Controls are age and race frequency-matched men who have a PSA < 3.0 ng/mL. Hip, spine and total body BMD is measured by Dual-energy X-ray Absorptiometry (DXA). Blood is used to obtain DNA. Polymerase Chain Reaction (PCR) techniques will be used to determine allelic distributions of genotypes for sex steroid metabolism, biosynthesis and action genes. Specifically, we are looking at polymorphisms in the androgen receptor, estrogen receptor, aromatase, 5-alpha reductase and CYP17 genes. Risk factor data are obtained by an in-person interview. Pathology information will be collected using standardized medical abstraction and all pathology will be confirmed by a central pathologist. Upon completion recruitment and data collection, we will evaluate the role of BMD and candidate genotypes in prostate cancer risk by race. We will further examine the interaction between BMD and genotypes to evaluate the hormonal environment – gene interaction and its effect on prostate cancer risk.

BODY:

In this section, we describe our accomplishments according to the Work Plan originally approved:

Task 1 Preparation for Study, Months 1-6:

- a. Obtain remaining IRB approvals
 - approval received from University of Pittsburgh and Maryland, but not from the DOD to commence recruitment in Baltimore
- b. Hire Pittsburgh project manager
 - Ms. Pamela Overberger hired
- c. Finalize agreements with Baltimore coordinator
 - contracted with UofMD Center for Clinical Trials for services of Ms. Jennifer De Santo two days per week.
- d. Finalize all instruments
 - done (Appendix A)
- e. Train interviewers to perform patient interviews using the instruments
 - doned

Task 2 Preparation for Data Entry, Months 6-12:

- a. Implement computerized data entry forms (interview, anthropometric, physical activity, pathology, DXA, and laboratory assay) in PoP
 - implementation in TeleForm completed

Task 3 Recruiting of Subjects and Obtaining of Data, Months 6-30

see tables 1-3 for summaries to date

Overall Study Progress:

We hired Pamela Overberger, MS, as the overall study coordinator. Ms. Overberger also serves as the Pittsburgh recruiter and interviewer. Drs. Modugno, Weissfeld and Ms. Overberger finalized the study

instruments (Appendix 1). Instead of using PoP as originally planned, we decided to use TeleForm, an automatic scanning data entry system. This enables us to scan data immediately and will save us time in data entry towards the end of the study period. Ms. Overberger developed the study Manual of Operations and works with all organizations to maintain study approval.

Pittsburgh Progress:

We obtained IRB approval from the University of Pittsburgh to commence recruitment of subjects in Pittsburgh. Recruitment began in February 2002. Cases are recruited from all newly diagnosed cases of prostate cancer seen in the practice of Dr. Joel Nelson. Controls are men who have participated in a population-based prostate cancer screening trial and are frequency matched to cases by age and race. The summary of recruitment to through August 2002 is in Table 1. We recruit approximately 4 men per week in Pittsburgh (2 cases, 2 controls), which is ahead of the anticipated recruitment schedule. Because interview data is scanned in weekly, we are able to provide interim data analyses. Table 2-3 summarizes the baseline data on recruited subjects through August 2002.

Baltimore Progress:

We obtained IRB approval from the University of Maryland in August, 2002. This was later than anticipated and has put our recruitment behind. Moreover, the DOD Human Subjects Committee has not yet approved adding Baltimore as a site for this study and we are therefore unable to commence recruitment of African Americans in Baltimore.

Nonetheless, in September 2002, Drs. Modugno and Weissfeld visited the Baltimore site to meet with the Baltimore PIs (Marc Hochberg, MD and Richard Alexander, MD) and study team. A part-time Baltimore study coordinator was hired (Ms. Jennifer DeSanto) through the University of Maryland Center for Clinical Trials. Ms. DeSanto will work with Dr. Alexander's staff in the urology clinic to recruit eligible African American cases. Ms. DeSanto will work two days per week (Thursday and Friday) when the urology clinic at the Baltimore VA takes place. Ms. DeSanto is paid only for the days she works and since recruitment has not begun, we have no costs associated with Ms. DeSanto to date. Ms. DeSanto received all the study instruments and instructions. During the first 2-3 weeks of recruitment, Ms. Overberger will go to Baltimore to provide onsite training of Ms. DeSanto (consenting and interviewing subjects).

Because of the late start of recruitment in Baltimore, Dr. Modugno has authorized that funds from Y1 of this grant that were to be used to support recruitment in Baltimore be set aside. This will ensure the availability of funds to continue recruitment in Baltimore after the 3 year study period ends (if need be). These funds will cover the cost of the study coordinator in Baltimore and all the associated study costs (DXAs, etc).

Once we begin recruitment in Baltimore, cases will be recruited from the VA urology clinic during their weekly clinic schedule (Thursdays and Friday mornings). Controls will be recruited from Dr. Hochberg's ongoing study of BMD in African American men. Controls will be frequency matched by age to cases.

Exclusion Criteria

The following are the criteria used to exclude men from participation in this study.

- <40 or >80 years of age
- Inability to consent to medical procedures.

one of which is labeled with a fluorescent dye (FAM, HEX or TET; Research genetics, Huntsville, AL). The products are resolved on the ABI 377 automated DNA sequencer (Applied Biosystems, Foster City, CA) and the resulting gel images are analyzed using the GENESCAN software package. These protocols are standard in Dr. Ferrell's lab. Genotypes are assigned by two independent readers by directly comparing test samples to sequence-verified control samples run on the same gel. Conflicts are resolved by repeat genotyping.

We have tested the laboratory assays on a sample of specimens early in our recruitment. The assays appear to be working.

BMD Measurments

Hip, spine and total body BMD will be measured by Dual-energy X-ray Absorptiometry (DXA) using a Hologic QDR-4500A (Hologic, Inc., Waltham, MA) in the Laboratory of Dr. Susan Greenspan. Quality control is assessed by daily quality control scans with the phantom provided by the manufacturer. We will also have a subset of scans (10%) reanalyzed by Synarc, Inc. (Bedford, MA), which provides quality control for large scale studies, including several of Dr. Greenspan's studies. All DXA results will be recorded on a standard study form for data entry.

Problems encountered and measures taken:

The major problem we have encountered is obtaining IRB approval for this study at Baltimore and the DOD. We have already received IRB approval in Baltimore. We are working with the DOD to receive approval to add Baltimore to the study so that we can begin recruitment at that site.

KEY RESEARCH ACCOMPLISHMENTS:

The study is well underway with all the components in place. We forsee successfully completing recruitment of Caucasians in Pittsburgh well within the study period. We anticipate successfully completing African American recruitment, although we anticipate that this may require an additional year due to the delay in recruitment in Baltimore because of the delay in receiving DOD IRB approval to add Baltimore as a site for this study.

REPORTABLE OUTCOMES:

None to date

CONCLUSIONS:

We are pleased with our progress and forsee the successful completion of this project. We are working with the DOD to receive IRB approval to begin recruitment in Baltimore.

REFERENCES:

None

APPENDICES:

Interview Questionnaire

Table 1: Summary of CASE and CONTROL Recruitment in Pittsburgh 2/01/02-8/31/02

	AA	Caucasian	Total
	AA	Caucasian	Iotai
Total CASES	13	98	95
Eligible Cases	13	85	83
Agreed to Contact	13 (100%)	74 (87%)	77 (93%)
Screened Enrolled Scheduled Ineligible Declined Excluded	10 8 (80%) 0 (0%) 2 (20%) 2	65 45 (69%) 5 (8%) 15 (23%) 8 7	72 49 (68%) 6 (8%) 17 (24%) 10 7
CONTROLS: Screened Enrolled Scheduled Ineligible Declined Excluded	10 8 (80%) 0 (0%) 2 (20%) 2	33 27 (82%) 3 (9%) 3 (9%) 0 3	43 35 (81%) 3 (7%) 5 (12%) 2 3

Table 2: Age and Race Distribution of Cases and Controls Recruited in Pittsburgh 2/1/02-8/31/02.

	Caucasian	Caucasian	African- American	African-American
Age Range	Cases	Controls	Cases	Controls
40-44	1			3
45-49	1			1
50-54	10		2	1
55-59	12	13	2	3
60-64	11	9	2	
65-69	5	5	1	
70-74	4	1	1	
75-79	1			
Total	45	28	8	8

Table 3: Summary Demographic Statistics on Cases and Controls (as of 8/16/02)

	Case (n=43)	Controls (n=35)
Age (years) (mean)	59.9	58.6
BMI (kg/m2) (mean)	27.8	31.1
Race		
AA	8	8
Caucasian	41	27
BMD (g/cm2)		
(mean)	1.01	1.04
Hip	1.07	1.11
Spine PA	1.18	1.20
Total		





General Information

int	e first section asks about your exerview, you have the right to re uncomfortable, or to end the i	general background. Throughout this efuse to answer any question that makes nterview at any time.
	StudyID	Date
City	1. Where were you born?	Case or Control? O Control O Case
State		Recruitment Site: O Pittsburgh UPMC
Country		O Pittsburgh VA O Baltimore VA

2. What is the race or ethnic background of each of your grandparents?

Father's father	Father's mother	Mother's father
O African-American	O African-American	O African-American
O Afro-Carribean	O Afro-Carribean	O Afro-Carribean
O Hispanic/Latino	O Hispanic/Latino	O Hispanic/Latino
○ White	O White	O White
() Asian	O Asian	O Asian
O Other	O Other	O Other
O Unknown	O Unknown	O Unknown

Mother's mother

- O African-American
- O Afro-Carribean
- O Hispanic/Latino
- O White
- O Asian
- O Other
- O Unknown



3. What is the highest grade or level of schooling you completed?
Oless than 8 years
○8 through 11 years
O 12 years or completed high school
O Post secondary vocational or technical training
O Some university or college
O College graduate
O Postgraduate
O Unknown
4. What is your current marital status?
O Never married
O Married or living as married
○ Widowed
O Divorced
○ Separated
5. How tall were you (without shoes) at age 18 (tallest adult height)?
feet inches
6. How much did you weigh when you were born?
O Less than 5 pounds
O 6 pounds to 7 pounds, 15 ounces
08 pounds to 9 pounds, 15 ounces
O 10 or more pounds
O Unknown
7. What was your weight at the age of 18?
nounds
pounds



8. What was your weight at about age 50? pounds
9. What was your maximum adult weight? pounds (The most you have weighed since the age of 18)
10. How old were you when you reached that maximum weight?
○18-29 years old
○ 30-39 years old
○ 40-49 years old
○50-59 years old
○ 60-69 years old
11. What was your minimum adult weight? pounds (The least you have weighed since the age of 18)
12. How old were you when you reached that minimum weight?
○18-29 years old
○30-39 years old
○40-49 years old
○50-59 years old
○ 60-69 years old
13. When you were born, were you: O Full term (about 9 month pregnancy)
O Four or more weeks premature
O Unknown

14. When you were born, were you a twin or triplet? O No

O Yes

O Unknown



- 15. Did your mother breast feed you when you were a baby?

 ONO OYes ODon't know
- 16. Did your mother smoke when she was pregnant with you?

 ONO OYes ODon't know
- 17. What is your birth order?

 Ofirstborn Osecond or more Odon't know
- 18. What hand do you write with?

 Oleft Oright Oboth
- 19. Which pair of pictures best describes your hair pattern at age 30?
 - O Picture 1-1 O Picture 2-6
 - O Picture 1-2 O Picture 2-7
 - O Picture 2-3 O Picture 3-2a
 - O Picture 2-4 O Picture 3-3
 - O Picture 2-5 O Picture 3-3a
 - O Picture 2-5a O Picture 3-4a
- 20. Which pair of pictures best describes your hair pattern at age 40?
 - O Picture 1-1 O Picture 2-6
 - O Picture 1-2 O Picture 2-7
 - O Picture 2-3 O Picture 3-2a
 - O Picture 2-4 O Picture 3-3
 - O Picture 2-5 O Picture 3-3a
 - O Picture 2-5a O Picture 3-4a



StudyID							

The following section asks about your personal medical history.

Medical History

1. Has your doctor ever told you that you have or have had:

If yes, are you currently being treated for this condition by a doctor?

A heart attack:	O No		
	O Yes	\bigcirc No	○ Yes
Angina:	O No		
	O Yes	\bigcirc No	O Yes
Congestive heart failure:	O No		
	O Yes	\bigcirc No	O Yes
Other heart disease:	O No		
	O Yes	O No	O Yes
Stroke:	O No		
	O Yes	O No	O Yes
Diabetes:	O No		
	O Yes	O No	O Yes
Parkinson's disease:	O No		
	O Yes	O No	() Yes
Dementia or Alzheimer's:	O No		
	O Yes	O No	○ Yes
Other neurologic disease:	O No		
	O Yes	O No	O Yes
Depression:	O No		
	O Yes	O No	○ Yes
COPD:	O No		
	O Yes	O No	() Yes
(Chronic obstructive pulmon asthma, emphysema)	ary disea	se, chr	onic bronchitis,
Arthritis of Hips:	O No		
	O Yes	O No	○ Yes
Arthritis of Knees	: O No		
	O Yes	O No	○ Yes



		St	udy	ID		

Arthritis of hands or arms:	O No	(Curren	tly under Trmt)
	O Yes	O No	O Yes
Osteoarthritis:	O No		
	O Yes	O No	O Yes
Rheumatoid arthritis:	O No		
Mediasora dronricus.	O Yes	O No	() Yes
		ONO	
Overactive thyroid:	O No		
or Grave's disease	O Yes	O No	O Yes
High blood pressure:	O No		
	O Yes	O No	O Yes
Underactive thyroid:	O No		
	() Yes	O No	O Yes
Hypogonadism:	O No		
(low blood testerone)	O Yes	O No	O Yes
Kidney stones:	O No		
	O Yes	O No	O Yes
Chronic kidney disease:	O No	1	***************************************
(or kidney failure)	O Yes	O No	O Yes
Intestinal problems:	O No	; ; ;	
(colitis)	O Yes	O No	O Yes
Stomach or duodenal ulcer:	O No	1	
	O Yes	ONo	○ Yes
Hepatitis:	O No] 	
	O Yes	ONo	O Yes
Cirrhosis:	O No		
	O Yes	O No	O Yes
Diverticulitis(osis):	O No	; ; ;	
	O Yes	O No	O Yes
Gall bladder stones:	O No	:	
(or inflammation)	O Yes	ОИО	O Yes
Sei zures:	∩ No	1	
. دی تک مرید	O Yes	O No	○ Yes
	·····]	······



		St	udy	ID		

Glaucoma:	O No	(Curr	ently under T'rmt)
	O Yes	\bigcirc No	○ Yes
Cataracts:	O No		
	O Yes	O No	○ Yes
Diseases of the retina:	O No		
<pre>(macular degeneration, detached retina)</pre>	○ Yes	O No	O Yes
Poor vision:	O No		
	O Yes	O No	O Yes
Osteoporosis:	O No		
	() Yes	O No	○ Yes

- 2. Have you ever been told you had cancer? ONo OYes (excluding basal cell skin cancer)
- 3. During a typical night in the last year, how many times did you usually wake up to urinate?
 - O Never
 - O Once

O Twice

O Three times

If more than once:

- O More than three times
- 3a. How old were you when you first began waking up to urinate more than once a night on a regular basis?
 - OLess than 30
 - 030-39
 - 040-49
 - 050-59
 - 60-69
 - 070 or older



	st	udyID	
d Conor	Page	and Bro	n+ n+ n

- 4. Over the past month or so, how often have you had to urinate again less than two hours after you finished urinating?
 - O Not at all
 - OLess than 1 time
 - O Less than half the time
 - O About half the time
 - O More than half the time
 - O Almost always
- 5. Over the past month or so, how often have you found that you have stopped and started again several times when you urinated?
 - O Not at all
 - O Less than 1 time
 - Oless than half the time
 - O About half the time
 - O More than half the time
 - O Almost always
- 6. Over the past month or so, how often have you found it difficult to postpone urination?
 - O Not at all
 - OLess than 1 time
 - OLess than half the time
 - O About half the time
 - O More than half the time
 - O Almost always



		St	udy	ID			

- 7. Over the past month or so, how often have you had a weak urinary stream?
 - O Not at all
 - OLess than 1 time
 - OLess than half the time
 - O About half the time
 - O More than half the time
 - O Almost always
- 8. Over the past month or so, how often have you had to push or strain to begin urination?
 - O Not at all
 - OLess than 1 time
 - Oless than half the time
 - O About half the time
 - O More than half the time
 - O Almost always
- 9. Has a doctor ever told you that you had a problem with your prostate?

ONo OYes

10. Has a doctor ever told you that you had an enlarged prostate or benign prostatic hypertrophy?

ONo OYes

1					were	you	when	a	doctor	first	told	you	that	you
had	this	prol	blem?	>		0	Less	th	an 30					
						0	30-39							
						0	40-49)						
						0	50-59	1						
						0	60-69)						
						0	70 or	. 0	lder					
						0								



		st	udy	ID			

11.	Has	a	doctor	ever	told	you	that	you	had	an	inflamed	prostate	or
pros	stati	Lti	Ls?										

ONo OYes

11a. If yes, how old were you when a doctor first told you that you had this problem?

Oless than 30

12. Have you taken the drug finasteride (PROCAR) for prostate problems?

 \bigcirc No

O Yes, but not currently

OYes, currently

O Don't know

13. Have you ever had any of the following surgical procedures of the prostate?

Biopsy: O No

O Yes

O Don't know

(Transurethral resection of the prostate)

TURP: O No

O Yes

O Don't know

Prostatectomy for benign disease:

 \bigcirc No

O Yes

O Don't know



		st	udy	ID		

Cancer KISK Baseline Questionnaire
Surgery for prostate cancer:
O No
() Yes
O Don't know
Prostate surgery, any other kind:
O No
O Yes
O Don't know
13a. If you have had any of these procedures, how old were you when you had any of these procedures for the first time?
O Less than 30
○ 30-39
○ 40-49
○ 50-59
○ 60-69
○70 or older
·
14. Have you had a vasectomy; that is, a sterilization procedure for men? ONo (Go to 15)
O Yes
14a. How old were you when you had a vasectomy?
O Less than 25
○ 25-34
○ 35-44
O45 or older



StudyID											

15. During	the past	three years, have you had a digital rectal exam?
		O No
		OYes, once
		O Yes, more than once
		O Don't know
	_	three years, have you had a blood test for example, a PSA?
		O No
		O Yes, once
		O Yes, more than once
		O Don't know
17. During	the past	12 months, have you been hospitalized overnight?
		O No
		··········O Yes
		O Don't know
17.a If yes overnight?	, how man	y different times have you been hospitalized One
		O Two or three
		O Four or five
		O Six or more
1		



		St	uay	ID		

Cancer Risk Baseline Questionnaire
Fracture History
The following section asks about broken bones in yourself or family members.
1. Has a doctor ever told you that you broke or fractured a bone?
ONo (Proceed to question 2)
O Yes
la. Has a doctor ever told you that you broke or fractured a HIP?
ONo
O Yes
How old were you when you broke or fractured your hip? If you broke or fractured your hip more than once, please tell me how old you were each time you broke your hip.
Age (years) How did you break your hip at this age?



studitD									

F					
1b. Has a doctor ever WRIST or FOREARM?	told you th	hat you b	roke or fr	actured your	
O No					
O Yes					
How old were you when forearm? If you broke once, please tell me h these bones.	or fracture	ed your w	rist or fo	rearm more th	han f
Age (years) How di	d you brea	k your wr	ist/forear	m at this ag	e?
		نـــــــــــــــــــــــــــــــــــــ			
1c. Has a doctor ever	told you th	hat you b	roke or fr	actured your	SPINE?
O Yes					
How old were you when broke or fractured yo old you were each tim	our spine m	ore than	once, plea		
Age (years)	How did yo	ou break	your spine	at this age	?
			- ,		1
	<u> </u>				



	St	udyID	
d C			

1d. Has a doctor ever	told you that you broke or fractured your SHOULDER
or COLLAR BONE?	
	○ No
	() Yes
	en you broke or fractured your shoulder/collar
	or fractured your shoulder/collar bone more
· -	ell me how old you were each time you broke
this bone.	
Age (years) Ho	w did you break your shoulder/collar bone at this age?
	
<u> </u>	
1e. Has a doctor ever	told you that you broke or fractured your UPPER
ARM?	O No
	O Yes
How old were you whe	en you broke or fractured your upper arm? If
	red your upper arm more than once, please tell
	each time you broke this bone.
	-
Age (years)	How did you break your upper arm at this age?
<u> </u>	



	st	udyID	
1 0		LL	

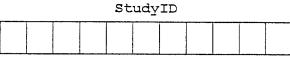
	told you that you broke or fractured your RIBS,
CHEST, OR STERNUM?	O No
	O Yes
	en you broke or fractured your ribs, chest, or see or fractured one of these bones more than
	how old you were each time you broke one of
these bones.	
How	did you break your ribs, chest or sternum at this
age: Age (years)	
I to the state of	
1g. Has a doctor ever LEG?	told you that you broke or fractured your UPPER
mme:	O No
	O Yes
How old were you wh	nen you broke or fractured your upper leg? If
	ared your upper leg more than once, please tell
me now old you were	e each time you broke this bone.
Age (years)	How did you break your upper leg at this age?
 	
<u> </u>	



StudyID							

11. Has a doctor ever told you that you broke or fractured your KNEE or KNEE CAP? ONO OYes How old were you when you broke or fractured your knee or knee cap? If you broke or fractured your knee or knee cap more than once, please tell me how old you were each time you broke this bone. Age (years) How did you break your knee or knee cap at this age? Age (years) How did you that you broke or fractured your LOWER CAPPERS ONO OYes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg? me how old you were each time you broke this bone. Age (years) How did you break your lower leg at this age?		
How old were you when you broke or fractured your knee or knee cap? If you broke or fractured your knee or knee cap more than once, please tell me how old you were each time you broke this bone. Age (years) How did you break your knee or knee cap at this age? II. Has a doctor ever told you that you broke or fractured your LOWER ONC OYES How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.		
How old were you when you broke or fractured your knee or knee cap? If you broke or fractured your knee or knee cap more than once, please tell me how old you were each time you broke this bone. Age (years) How did you break your knee or knee cap at this age? II. Has a doctor ever told you that you broke or fractured your LOWER ONC OYES How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.		() Yes
Age (years) How did you break your knee or knee cap at this age?	cap? If you broke once, please tell	e or fractured your knee or knee cap more than
1i. Has a doctor ever told you that you broke or fractured your LOWER LEG? ONO OYes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.	Age (years)	w did you break your knee or knee cap at this age?
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower tell me how old you were each time you broke this bone.		
O No O Yes How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.		told you that you broke or fractured your LOWER
How old were you when you broke or fractured your lower leg? If you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.	TEG ;	Оио
you broke or fractured your lower leg more than once, please tell me how old you were each time you broke this bone.		O Yes
Age (years) How did you break your lower leg at this age?	you broke or fract	ured your lower leg more than once, please tell
	Age (years)	How did you break your lower leg at this age?





	told you that you broke or fractured your ANKLE,											
FOOT, or TOES?	O No											
	O Yes											
toes? If you broke	nen you broke or fractured your ankle, foot, or or fractured your ankle, foot or toes more than ne how old you were each time you broke this											
bone.												
Age (years) How	did you break your ankle, foot or toes at this age?											
												
·												
1k. Has a doctor eve	r told you that you broke or fractured your HAND or											
FINGERS?	O No											
	O Yes											
How old were you whe	n you broke or fractured your hand or fingers?											
If you broke or frac	tured your hand or fingers more than once,											
please tell me how o	ld you were each time you broke this bone.											
Total Constant	w did you brook your hand on Singana at this area											
Age (years) How	w did you break your hand or fingers at this age?											
\												
 												
												



StudyID												

11. Has a doctor ever told you that you broke or fractured a bone that													
is not on this list? ONO													
O Yes													
If yes, what bone:													
How old were you when you broke or fractured this bone? If you													
broke or fractured this bone more than once, please tell me how													
old you were each time you broke this bone.													
Age (years) How did you break this bone at this age?													
2. Was your natural mother ever told by a doctor that she had osteoporos: sometimes called thin or brittle bones? Please answer for your natural	LS,												
mother—the mother who gave birth to you.													
O No O Yes O Don't Know													
2 Did your potumal method over basel on forestone a basel Discussion													
3. Did your natural mother ever break or fracture a bone? Please answer for your natural mother—the mother who gave birth to you.													
ONG OVER OBERTA Know													
O No O Yes O Don't Know													
3a. Did your natural mother ever break her hip?													
O No O Yes O Don't Know													
3b. Did your natural mother ever break her wrist?													
ONO OYes ODon't Know													



_	StudyID												
1													
	-				·		•	·		·	·		

3c. Did your natural mother ever break her spine? ONO OYes ODon't Know							
3d. Did your natural mother ever break a bone not listed above? ONO OYes ODon't Know							
If yes, what bone:							

4. Is your natural mother still alive?

£	() NO
	O YesHow old is your natural mother now?
	O Don't Know years
How old	was your natural mother when she died?
	years

5. Was your natural father ever told by a doctor that he had osteoporosis, sometimes called thin or brittle bones?

O No O Yes O Don't Know

6. Did your natural father ever break or fracture a bone?

O No O Yes O Don't Know

- 6a. Did your natural father ever break his hip?

 ONo OYes ODon't Know
- 6b. Did your natural father ever break his wrist?

 O No O Yes O Don't Know



	StudyID
26	
Bone Mineral Density, Sex Steroid Ge Cancer Risk Baseline Que	nes, Race, and Prostate stionnaire
6c. Did your natural father ever break	
ONo OYes ODon't Know	
6d. Did your natural father ever break	
O No O Yes O Don't	: Know
Please specify:	
7. Is your natural father still alive?O No	
OYesHow old is	your natural father now?
ODon't Know	1 Incorporate Tachief Hows
<u> </u>	years
How old was your natural father when h	ne died?
The second second register when i	ie uleu:
years	
How many full brothers do you have?	
hese are brothers related by blood, not	half-brothers or step-brothers.
<pre>8a. Did any of your full brothers e fracture his hip? O No</pre>	ver break or
O Yes	
O Don't Know	
First name	Age when broken



9.

Bon	e Mineral	Dens	ity,	Sex	x Ste	roid Ge	nes,	, I	Race	⊇,	and	Pros	tat	e			
	Bone Mineral Density, Sex Steroid Genes, Race, and Prostate Cancer Risk Baseline Questionnaire																
	8b. Did any of your full brothers ever break or fracture his wrist?																
ļ	O No																
	O Yes																
	O Don't Know																
	First name Age when broken																
		First	t na	me	1 1 1 -		A	ge '	whe	n b	roken —	1					
		· · · · · · · · · · · · · · · · · · ·		<u>-</u>				L.									
													J				
	How many	full	sis	ters	do y	ou have	?										
/ m/h				7 	1 1 1	. 7 7	<u> </u>										
/ T116	ese are s	ıster:	s re	Iatec	ı by ı	этооа, 1	not	naı	.I-s	ist	ers (or s	tep.	-si:	ste:	rs.	•
	a. Did ar			r ful	l sis	ters ev	rer :	bre	ak	or							
1	racture 1	ier ni	.pr	ON	•												
				O Ye	es												
				O Do	on't	Know											
	-						_			_	_						
		'irst	name	<u>•</u> 	- 1		Age	wh —	en	bro	ken						
			T						T								
									1								

StudyID



StudyID												

Bone Mineral Density, Sex Steroid Genes, Race

Cancer Risk Baseline Questio	
9b. Did any of your full sisters efracture her wrist?	ver break or
O No	
○ Yes	
○ Don't Know	
•	
First name	Age when broken



StudyID												

Family History

	This section a	sks about vou	ır familv medi	cal historv.	
1. How	many brothers	and half-bro	thers do you h	nave?	
	O None	O Four			
	One	OFive or	more		
	O Two	O Don't kno	ow		
	O Three	•			
2. How	many sisters a	nd half-sist	ers do you hav	re?	
	O None	O Four			
	O One	O Five or mo	ore		
	O Two	O Don't know	₹		
	O Three				
3 11011 11	aana da wa	a harra?	A How many d	loughtone do w	ou barro?
	nany sons do yo ne OThree	u Have:	. –	O Three	ou nave:
_	e OFour		-	-	
_			O One	-	
O Tw	o Ofive or m	ore	O Two	O Five or mor	:e
or half-	any of your pa sisters ever be on of basal cel	een diagnosed	d with any typ		
		O No			
		O Yes			
		O Don't	Know		
	any of your pa -sisters ever b				s, sisters
		O No			
		○ Yes			
		O Don't	Know		



		st	udy	ID			
 	 			İ	L	L	

The following questions ask about relatives who may have had cancer.

7. Have any of the following relatives ever had cancer: father, mother, son, daughter, brothers, sisters, half-brothers, or half-sisters? Please tell me about any episodes of cancer except basal cell skin cancer.

	(Code)	(Code)	(Years)
1st Relative			
	Relationship	Type of Cancer	Age
2nd Relative	Relationship	Type of Cancer	Age
3rd Relative	Relationship	Type of Cancer	Age
4th Relative	Relationship	Type of Cancer	Age
5th Relative			
	Relationship	Type of Cancer	Age
6th Relative	Polationship	Type of Cancer	
	Relacionship	Type of Cancer	Age
7th Relative	Relationship	Type of Cancer	Age
8th Relative	Relationship	Type of Cancer	Age



		st	udy	ID		

Health Habits

The following section asks about some of your health habits.

1. Have you ever smoked cigarettes regularly for six months or longer?
O No
O Yesla. At what age did you start smoking cigarettes regularly?
years
1b. During periods when you smoked, how many cigarettes did or do you usually smoke per day?
O 1-10
0.11.20
O 11-20
○ 21-30
O 31-40
○ 41-60
○ 61-80
O81 or more
1c. Do you smoke cigarettes regularly now?
○ No ○ Yes
1d. At what age did you stop smoking cigarettes
regularly?
years

- 2. Do you now or did you ever smoke a pipe regularly for a year or longer?
- O I never smoked a pipe regularly for a year or more.
- O I did smoke a pipe regularly for more than a year, but currently I do not smoke a pipe.
- O I currently smoke a pipe.



		st	udy	ID		

3. Do you now or longer?	did you ever smoke cigars regularly for a year or						
OI never smoked ci	gars regularly for a year or more.						
OI did smoke a ciq	gars regularly for more than a year, but currently I do not smoke cigars.						
OI currently smoke	e cigars pipe.						
4. On average, he your TEEN-AGE yes	ow many glasses of milk did you consume per day during ars?						
	O none						
	Oless than 1 glass per day						
	O one glass per day						
	O two glasses per day						
	O three or more glasses per day						
5. On average, hyour TWENTIES?	ow many glasses of milk did you consume per day in						
	O none						
	Oless than 1 glass per day						
	O one glass per day						
	O two glasses per day						
	O three or more glasses per day						
	how many glasses of milk did you consume per day in						
your FIFTY'S?	O none						
	Oless than 1 glass per day						
	Oone glass per day						
	O two glasses per day						
	O three or more glasses per day						
	O not applicable						
7. On average,	how many glasses of milk do you consume NOW?						
	O none						
	Oless than 1 glass per day						
	Oone glass per day						
	O two glasses per day						
	O three or more glasses per day						
	O not applicable						



	stud	YID		

	Cancer Alak Baserine Questionnaire
	o you currently drink regular coffee? (Not decaffinated)
	8a. How many cups of regular coffee do you drink per day?
	cups
a D	o you currently drink regular tea?
	_
O No	O Yes (Not herbal or decaffinated)
	9a. How many cups of regular tea do you drink per day?
	cups
	Do you currently drink sodas that contain caffeine such as i, Coca-Cola, Tab, and Mountain Dew?
O No	○ Yes
	10a. How many cans of caffeinated soda do you drink per
	day?
	cans
11.	Have you ever consumed alcohol on a regular basis?
O No	O Yes
0 2.10	(Drinking at least once a week for 6 months or more)
	11a. How old were you started drinking alcohol on a weekly
	basis?
	years
	11b. For how many years have you or did you comsume alcohol on a weekly basis?
	years



	StudyID										
1	Conos	Page	and	Prostate							

11c.	How many alcoholic drinks per week did you or do you consume?
	(One drink = 12 oz. of beer, 4 oz. of wine, or 1.5 oz. of hard liquor)
	drinks per week



Scaayin										
									<u> </u>	

CHARACTE

Bone Mineral Density, Sex Steroid Genes, Race, and Prostate Cancer Risk Baseline Questionnaire

Physical Activity

The next section asks about physical activity and exercise.

1. How many hours per week did you usually spend WALKING at age:

14-17 years (high school):

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

18-21 yrs. (college):

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

22-29 yrs.:

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

30-39 yrs.:

O 0 hrs/week O <1 hr/week O 1-3 hrs/week O 4-6 hrs/week O >6 hrs/week

40-49 yrs.:

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

50+ yrs.:

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

Next, I will ask you to consider the time you have spent doing all other common activities and/or sports EXCEPT walking. (These activities may include hiking; jogging or running; swimming; sking; bicycling; skating; raquetball; squash; badminton; any dancing, including exercise classes such as aerobic dance; gardening; golf, with or without a cart; bowling; rowing; shuffleboard; canoeing; calisthnenics; softball; field hockey; basketball; tennis; weightlifting; nautilus; volleyball; horseback riding; or any other).

2. How many hours per week did you regularly spend participating in the above activities between the ages of:

14-17 years (high school):

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week

18-21 yrs. (college):

00 hrs/week 0<1 hr/week 01-3 hrs/week 04-6 hrs/week 0>6 hrs/week



StudyID										

22-29 yrs.:

O hrs/week O<1 hr/week O 1-3 hrs/week O 4-6 hrs/week O>6 hrs/week

30-39 yrs.:

O hrs/week O<1 hr/week O 1-3 hrs/week O 4-6 hrs/week O>6 hrs/week

40-49 yrs.:

O hrs/week O<1 hr/week O 1-3 hrs/week O 4-6 hrs/week O>6 hrs/week

50+ yrs.:

O hrs/week O<1 hr/week O 1-3 hrs/week O 4-6 hrs/week O>6 hrs/week

3. In general, how many hours per day do you usually spend watching television?

hours

4. Over this past year, have you spent more than one week confined to a bed or chair as a result of an injury, illness, or surgery?

ONo OYes

4a. How many weeks over this past year were you confined to a bed or chair?

5. Do you have difficulty doing any of the following activities?

weeks

- a. Getting in or out of bed or a chair: ONo OYes
- b. Walking across a small room without resting: ONo OYes
- c. Walking for 10 minutes without resting: () No () Yes



classes)?

			StudyID											
Bone Mineral	Density, Cancer Ri				,		,	a	nd	Pro	sta	te		

6. Did you ever compete in an individual or team sport (not including any time spent in sports performed during school physical education

O No	O Yes
	6a. How many total years did you participate in competitive sports?
	years



StudyID										
				L			l	L		

Weight Loss

The following section asks about losing weight.

- 1. Are you currently trying to lose weight?
- \bigcirc No
- O Yes

If yes, what metho	ds are you using to lose	weight?
Diet: O No	Diet pills: O No	Diet liquids: () No
○ Yes	O Yes	O Yes
		Other: O No
Exercise: O No	Diet program: O No	O Yes
O Yes	O Yes	
t		If other, specify:

2. The next question concerns any weight you have lost ON PURPOSE since you turned 50. Have you lost...

50+ lbs.:

O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times

20 to 49 lbs.:

O Never \bigcirc 1-2 times \bigcirc 3-4 times \bigcirc 5-6 times \bigcirc 7+ times

10 to 19 lbs.:

O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times

5 to 9 lbs.:

O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times



StudyID

Bone Mineral Density, Sex Steroid Genes, Race, and Prostate Cancer Risk Baseline Questionnaire

3. The next question concerns weight you have lost WITHOUT TRYING since you turned 50. Have you lost...

50+ lbs.:

- \bigcirc Never \bigcirc 1-2 times \bigcirc 3-4 times \bigcirc 5-6 times \bigcirc 7+ times
- 20 to 49 lbs.:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- 10 to 19 lbs.:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- 5 to 9 lbs.:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- 4. The next question concerns any weight loss of 20 or more pounds since you turned 50. Have you lost 20 or more pounds by using:
- a. diet pills:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- b. a liquid diet:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- c. weight loss program:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- d. starvation or fasting:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- e. other low calorie diet:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- f. exercise:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- g. depression or stress:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- h. stomach or intestinal surgery:
- O Never \bigcirc 1-2 times \bigcirc 3-4 times \bigcirc 5-6 times \bigcirc 7+ times
- i. illness:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times



StudyID									

- 5. The next question concerns any weight loss of 20 or more pounds you may have experienced between the ages of 40 and 49. Did you lose 20 or more pounds by using:
- a. diet pills:
- \bigcirc Never \bigcirc 1-2 times \bigcirc 3-4 times \bigcirc 5-6 times \bigcirc 7+ times
- b. a liquid diet:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- c. weight loss program:
- O Never O1-2 times O3-4 times O5-6 times O7+ times
- d. starvation or fasting:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- e. other low calorie diet:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- f. exercise:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- g. depression or stress:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- h. stomach or intestinal surgery:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- i. illness:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- 6. The next question concerns any weight loss of 20 or more pounds you may have experienced between the ages of 18 and 39. Did you lose 20 or more pounds by using:
- a. diet pills:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- b. a liquid diet:
- O Never 01-2 times 03-4 times 05-6 times 07+ times
- c. weight loss program:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- d. starvation or fasting:
- O Never 01-2 times 03-4 times 05-6 times 07+ times



studito										
				L	L		L	l	L	

- 6. (18 and 39 cont'd)
- e. other low calorie diet:
- O Never 01-2 times 03-4 times 05-6 times 07+ times
- f. exercise:
- O Never 01-2 times 03-4 times 05-6 times 07+ times
- g. depression or stress:
- O Never 01-2 times 03-4 times 05-6 times 07+ times
- h. stomach or intestinal surgery:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- i. illness:
- O Never O 1-2 times O 3-4 times O 5-6 times O 7+ times
- 7. People's weight changes during their adult lives. During your ADULT life, would you say that:
- O Your weight has stayed about the same (within 10 lbs.)
- O You have had a gradual gain in weight (more than 10 lbs.)
- O You have had a gradual loss in weight.
- O You have had a marked weight loss and kept it off.
- O Your weight has repeatedly gone up and down.



		Stu	gĀTD		
L		<u> </u>			
d	Genes,	Race,	and	Prostate	

Medication Inventory Form

The following questions in this section ask about the medicines you take. As part of this study, we are examining prescription and over-the-counter medications used by study participants. These include pills, dermal patches, creams, salves, injections, inhalers and suppositories.

1. Are these all the prescription and non-pr	escription	on medica	tions
that you took in the last 30 days?			
O No O Yes O Took no medicine			
If no, subject called and MIF administered:	/	/	
22 ,	mo	da	ĀL

First we will consider medicine for arthritis, headaches, and other aches and pains. Please look at this list of medications.

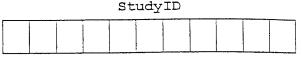
ASPIRIN
ASPIRIN PLUS CODEINE
ANACIN
ASCRIPTIN
BUFFERIN
ANOTHER ASPIRIN

2. In the past 12 months, have you taken any of these at least once a week?

ONo OYes

						the second secon		
	If yes, about how me one of these medic	per	week	r	on	average,	did	you
	○ 5-7 days							
	○1-4 days							
	O Don't know							
	1							
1		 						





3. Have you EVER taken any of the medications on this list every day or almost every day for a year or longer? (It does not have to be the same one every day).

ONO OYes

3.a If yes, for how many years did you take one of these every day or almost every day?

yrs

Look at this list of medications for pain, arthritis, headaches and other discomfort.

TYLENOL
TYLENOL PLUS CODEINE
ANACIN III
ACETOMINOPHEN
ANOTHER ASPIRIN SUBSTITUTE

4. In the past 12 months, have you taken any of these at least once a week?

ONo OYes

4.a If yes, about how many days per week , on average, did you take one of these medications?

O 5-7 days
O 1-4 days
O Don't know

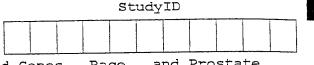
5. Have you EVER taken any of the medications on this list every day or almost every day for a year or longer? (It does not have to be the same one every day).

ONo OYes

5.a If yes, for how many years did you take one of these every day or almost every day?

yrs





Look at this list of medications for pain, arthritis, headaches, and other discomforts:

ADVIL	DATRIL	MEDIPREN	NUPRIN	IBUPROFIN NAPROXEN TOLMETIN	PHENYLVUTAZONE
VOLTARIN	NALFON	FENOPROFEN	NAPROSYN		MECLOFENMATE
FELDENE	PRIOXICAM	DOLOBID	TOLECTIN		MELAMIN
BUTAGEN	BUTAZOL	BUTAZONE	DIFUNISAL	AZOLID	

6. In the past 12 months, have you taken any of these at least once a week?

ONo OYes

6.a If yes, about how many days per week , on average, did you take one of these medications?

- 05-7 days
- 01-4 days
- O Don't know

7. Have you EVER taken any of the medications on this list every day or almost every day for a year or longer? (It does not have to be the same one every day).

ONo OYes

7.a If yes, for how many years did you take one of these every day or almost every day?

Yrs



StudyID							
			1				

Look at this list of medications for pain, arthritis, headaches, and other discomforts:

MOTRIN RUFEN ANOTHER PRESCRIPTION IBUPROFIN PRODUCT

8. In the past 12 months, have you taken any of these at least once a week?

ONo OYes

8.a If yes, about how many days per week , on average, did you take one of these medications?

05-7 days

01-4 days

O Don't know

9. Have you EVER taken any of the medications on this list every day or almost every day for a year or longer? (It does not have to be the same one every day).

ONo OYes

9.a If yes, for how many years did you take one of these every day or almost every day?

yrs



	StudyiD									
L						L			 İ]

Look at this list of medications for pain, arthritis, headaches, and other discomforts:

SULINDAC
CLINORIL
INDOCIN
INDOMETHACIN

10. In the past 12 months, have you taken any of these at least once a week?

ONo OYes

10.a If yes, about how many days per week , on average, did you take one of these medications?

- 05-7 days
- 01-4 days
- O Don't know

11. Have you EVER taken any of the medications on this list every day or almost every day for a year or longer? (It does not have to be the same one every day).

ONo OYes

11.a If yes, for how many years did you take one of these every day or almost every day?

yrs



studyin							

Prescription Medication

List the name of the prescription medicine, the strength, and the total number of doses taken per day, week or month during the LAST 30 DAYS..

٦.	Code	Name		
1)				
	strength:		per:	PRN?
		quantity used:	O day	O No
		O week O month	○ Yes	
			Omonen	
		Reason for use:		
	Code	Name		
2)				7
			•	
	strength:		per:	PRN?
		quantity used:	O day	Оио
			O week	O Yes
	æ	eason for use:	O month	4
			ı	
	Code	Name		
3)				
			per:	PRN?
_	strength:		O day	O No
		quantity used:	O week	O Yes
_			O month	1
		_		
_	Re	ason for use:		



StudyID							

		Cancer Kisk Baseline Quest	ionnaire
	Code	Name	
4)			
	strength:		per: PRN?
			O day O No
		quantity used:	O week O Yes
	F	eason for use:	O month
			ı
5)	Code	Name	
			per: PRN?
	strength:		O day O No
		quantity used:	O week O Yes
			Omonth
	F	Reason for use:	Omorran
6)	Code	. Name	
-,			
	strength:		per: PRN?
		quantity used:	O day O No
		quartersy used.	O week O Yes
	1	Reason for use:	O month
7)	Code	Name	
',			
	haran and the same		per: PRN?
Г	strength:		O day O No
		quantity used:	O week O Yes
	R€	eason for use:	O month
i			



StudyID									

Over-the-Counter Medications

Copy the name of the non-prescription medicine, the strength, and the total number of doses taken per day, week or month during the last 30 days. Include aspirin, or aspirin-containing medicines such as Bufferin, Anacin, or Ascriptin, laxatives, sleeping pills, antacids and antihistimines.

1)	Code	Name		
-,				
	strength:	quantity used:	per: PRN? O day O No O week O Yes	
		Reason for use:	O month	
2)	Code	Name		_
-,				
	strength:	quantity used:	per: PRN? O day O No O week O Yes O month	
		Reason for use:	1	
3).	Code	Name		
	strength:		per: PRN?	
		quantity used:	Oday Ono	
		Reason for use:	○ week ○ Yes ○ month	
			<u> </u>	



studyin									

		Cancer Risk Baseline Questionnai	re	
4)	Code	Name		
•				
	strength:		per:	PRN?
		quantity used:	O day	O No
			O week	○ Yes
		Reason for use:	O month	1
	Code	Name		
5)				
	strength:		per:	PRN?
		quantity used:	O day	O No
			O week	O Yes
		Reason for use:	O month	1
			•	
~	Code	Name		
6)				
	strength:		per:	PRN?
		quantity used:	O day	O No
	LL	Reason for use:	O week	() Yes
			○ month	•
7)	Code	Name		1
••				
	strength:		per:	PRN?
		quantity used:	O day O week	○ No ○ Yes
		Reason for use:	O month	



StudyID										
	1	 		L	<u> </u>	L	L		l	<u> </u>

Vitamin and Mineral Supplements

List all vitamins, minerals, herbal preparations, and other supplements taken during the last 30 days.

			Quantity	
1)	Code	Name	used per:	
			O day	
			O week	
	Strength:		O month	
2)	Code	Name	Quantity used per:	
2)			O day	
			O week	
	Strength:		O month	
			Quantity	
3)	Code	Name	Quantity used per:	
3)	Code	Name		
3)	Code	Name .	used per:	
3)	Code Strength:	Name .	used per:	
3)		Name .	used per: Oday Oweek	
3)		Name .	used per: Oday Oweek	
3)	Strength:		used per: Oday Oweek	
3)		Name	used per: Oday Oweek Omonth Quantity used per:	
	Strength:		Quantity used per: Oday Oweek Omonth Quantity used per: Oday	
	Strength: Code		Quantity used per: Oday Omonth Quantity used per: Oday Oweek	
	Strength:		Quantity used per: Oday Oweek Omonth Quantity used per: Oday	
	Strength: Code		Quantity used per: Oday Omonth Quantity used per: Oday Oweek	



StudyID										

		Cancer Ars	sk pasellile	Ques croi	marre	
5)	Code Strength:	N:	ame	Qu	uantity used	per: O day O week O month
6)	Code Strength:	N:	ame	Qı	uantity used	per: Oday Oweek Omonth
7)	Code Strength:	Na	ame	<u>o</u> n	uantity used	per: Oday Oweek Omonth
8)	Code Strength:	Na	ame	Q1	uantity used	per: Oday Oweek Omonth



StudyID

Bone Mineral Density, Sex Steroid Genes, Race, and Prostate Cancer Risk Baseline Questionnaire

Blood Collection

1. Date blood drawn:	2. Drawn By:
/ / /	
mo da yr	
3. Time Drawn:	O AM O PM
hr min	

4. How long since you had anything to eat or drink besides water?



5. Have you engaged in any vigorous physical activity in the last eight hours?

ONo OYes

6. Have you taken any aspirin or anti-inflammatory agents in the last forty-eight hours?

ONo OYes





	StudyID										
Genes	Race	and Prostato									

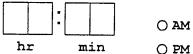
Blood Processing

RED TOP TUBES: Red top tubes should be held at room temperature to allow clot formation; they should then be centrifuged for 15 minutes at $1,200 \times g$ (2,400-3,000 RPM). Tubes not centrifuged immediately after clot formation should be refrigerated. After centrifugation, tubes should be refrigerated until serum and clot is aliquoted into the appropriate cryovials and frozen at -70 degrees Centigrade.

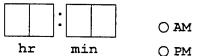
LAVENDER and GREEN TOP TUBES: These tubes should be refrigerated immediately or centrifuged. Centrifuge for 15 minutes at $1,200 \times g$ (2,400-3,000 RPM). Samples should be aliquoted immediately after centrifugation or refrigerated until they can be aliquoted. Freeze aliquots at -70 degrees Centigrade.

/.	втоо	a pr	oce	ssed	by:	

8. Time Centrifugation begun:



9. Time sample placed in cryovials:



10. Time cryovials placed in freezer:





StudyID										

Anthropometry							
1. WAIST (natural waist): 1st Measurement (cm.):							
2nd Measurement (cm.):							
If the difference between the 1st and 2nd measurements is >3 cm, repeat both measurements.							
Repeat 1st Measurement (cm.):							
Repeat 2nd Measurement (cm.):							
2.ADBOMEN (iliac crest or umbilicus): 1st Measurement (cm.):							
2nd Measurement (cm.):							
If the difference between the 1st and 2nd measurements is >3 cm, repeat both measurements.							
Repeat 1st Measurement (cm.):							
Repeat 2nd Measurement (cm.):							



	Stud	yID	

3. HIP (greater trochanter or greatest width of buttocks):								
1st Measu	rement (cm.):							
2nd Measu	rement (cm.):							
	If the difference between the 1st and 2nd measurements is >3 cm, repeat both measurements.							
	Repeat 1st Measurement (cm.):							
	Repeat 2nd Measurement (cm.):							
using the 1	(measure without shoes at the peak of a deep inhalation Harpenden Stadiometer):							
Participant	-							
Offorward	O Sideways O Unable If unable, explain:							
1st Measu	rement (cm.):							
2nd Measu	rement (cm.):							
	If the difference between the 1st and 2nd measurements is >4 cm, repeat both measurements.							
	Repeat 1st Measurement (cm.):							
	Repeat 2nd Measurement (cm.):							



StudyID									

5. BODY WEIGHT (measure without shoes or heavy clothing):							
Participant Weighed: O No O Yes							
If not done, explain:							
1st Measurement (kg.): 2nd Measurement (kg.):							
If the difference between the 1st and 2nd measurements is >4 kg, repeat both measurements.							
Repeat 1st Measurement (kg.):							
Repeat 2nd Measurement (kg.):							



studyid										
L	L	L	l .		1		L	L	L	L

Bone Density Scan

1. Date of Scan:	2. Performed by:
/ / /	
mo da yr	
3. Have you had any fracture or	replacement of the following:
3.1 Femur?	
○ No	
○ Yes Which Side? ○ Left	O Right O Both
3.2 Hip?	
O No	
O Yes Which Side? O Left	O Right O Both

4. Do you have any metal objects, such as staples or a pacemaker, in the area of the abdomen?

ONO OYes

(If hip replacement on both sides, do not do bone scan.)

5. Have you had any of the following tests within the past ten days?

(If yes to any, DEXA will need to be re-scheduled.)

- a. barium enema: O No O Yes
- b. upper GI X-ray series: O No O Yes
- c. lower GI X-ray series: O No O Yes
- d. nuclear medicine scan: O No O Yes
- e. other tests using dye or radioactive material: O No O Yes



17100	
Bone Mineral Density, Sex Steroid Genes Cancer Risk Baseline Questi	
6. Bone Density Measurement Completed for:	
6.1 Hip? O No O Yes	
6.1.1 Scan No:	6.5 Lean Body Mass:
6.1.2 BMD:	kg
6.2 Spine-lateral? () No () Yes	6.6 Percent Body Fat:
6.2.1 Scan No:	
6.2.2 BMD:	
6.3 Spine-PA? () No () Yes	
6.3.1 Scan No:	
6.3.2 BMD:	
6.4 Total Body? () No () Yes	
6.4.1 Scan No:	·
6.4.2 BMD:	
Special Considerations:	· · · · · · · · · · · · · · · · · · ·

StudyID